K102751

FEB 1 1 2013

CERAGEM MEDISYS

CERAGEM Medisys Inc.
www.ceragemmedisys.com

510(k) Summary

In accordance with the requirements of 21 CFR.807.92, the following information about 510(k) safety and effectiveness is being submitted.

1. Submitter

CERAGEM Medisys Inc.
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Contact Person: Mi - Suk Park

2. Date Prepared

February 11, 2013

3. Device Name

Common name : LabonaCheck Gluppy Blood Glucose Monitoring System
LabonaCheck Gluppy Control Solution

Classification : Class II (Regulation: 21 CFR § 862.1345)
Class I (Regulation: 21 CFR § 862.1660)

Product Codes : NBW(Blood Glucose Test System, Over the Counter), CGA
JJX

4. Predicate Device

LabonaCheck® Gluppy Blood Glucose Monitoring System is substantially equivalent to The RIGHTEST BLOOD GLUCOSE MONITORING SYSTEM described as below.

(1) Device Name: RIGHTEST BLOOD GLUCOSE MONITORING SYSTEM,

(2) Model: GM 100

(3) Manufacturer: BIONIME CORPORATION

(4) 510(K) Number: K081451

5. Device Description

The system consists of Test Meter, Test Strips, Code key, Lancing Device, lancets, 3V battery and Carrying Case.

The system measures the amount of glucose (sugar) in whole blood. Blood is applied to the

absorbent hole of the test strip and automatically drawn into the reaction zone where reaction between reagent and glucose occurs.

6. Indication for use

The LabonaCheck® Gluppy Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip. The LabonaCheck® Gluppy Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

The LabonaCheck® Gluppy Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The LabonaCheck® Gluppy Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use.

The LabonaCheck® Gluppy Blood Glucose Test Strips are for use with the LabonaCheck® Gluppy Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip.

The LabonaCheck® Gluppy Control Solution is for use with the LabonaCheck® Gluppy Blood Glucose Monitoring System as a quality control check to verify that the meter and test strips are working together properly.

7. Comparison to Predicate Device

Comparison		
Item	**Device**	**Predicate**
Device Name	LabonaCheck® Gluppy	RIGHTEST GM100
Similarities		
Detection Method	Amperometry	Amperometry
Enzyme	Glucose Oxidase (Aspergillus niger)	Glucose Oxidase (Aspergillus niger)
Mediator	Potassium ferricyanide	Potassium ferricyanide
Test range	20~600 mg/dL	20~600 mg/dL
Temperature range	50~104°F 10~40°C	50~104°F 10~40°C

Sample Volume	1.0 uL	1.4 uL
Humidity range	Below 80%	10~90%
Electrode	Noble metal electrode	Noble metal electrode
Warranty(Test Meter)	3 years	3 years
Power(Battery)	CR2032	CR2032
Differences		
Open use time (Test Strips)	4 months	3 months
Coding	Code Key	No coding
Test Time	5 second	8 second
Hematocrit range	20~60%	30-55%
Memory	500 blood glucose test results with date and time	10 blood glucose test results with date and time

Conclusion

As shown in the comparison table, the LabonaCheck® Gluppy Blood Glucose Monitoring System and the RIGHTEST GM100 have the same detection method, test range, temperature range, electrode and batteries. Furthermore, the LabonaCheck® Gluppy Blood Glucose Monitoring System also uses the same enzyme and mediator as the RIGHTEST GM100. To sum up the similarities, the LabonaCheck® Gluppy Blood Glucose Monitoring System is similar with the predicate device because most of the specifications deciding the characteristics of the device are the same. In conclusion, despite the differences such as open use time, coding, test time, etc. the LabonaCheck® Gluppy Blood Glucose Monitoring System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 11, 2013

Ceragem Medisys Inc.
c/o Grace Kim
Ceragem International Inc.
3699 Wilshire Blvd., Suite 930
Los Angeles, CA 90010

Re: k102751
Trade/Device Name: LabonaCheck Gluppy Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, CGA, JJX
Dated: January 28, 2013
Received: February 07, 2013

Dear Ms. Kim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): k102751

Device Name: LabonaCheck Gluppy Blood Glucose Monitoring System

Indications for Use:

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The LabonaCheck Gluppy Blood Glucose Test Strips are for use with the LabonaCheck Gluppy Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip.

The LabonaCheck Gluppy Control Solution is for use with the LabonaCheck Gluppy Blood Glucose Monitoring System as a quality control check to verify that the meter and test strips are working together properly.

Prescription Use _____ AND/OR Over-The-Counter Use __X___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Devices and Radiologic Health (OIR)

Katherine Serrano

Division Sign-Off
Office of In Vitro Devices and Radiologic Health

510(k) k102751